

**REMARKS**

Of claims 1-42 which were contained in the pending application, claims 21, 24, 27, and 31-35 are cancelled. The informalities contained claims 18, 23, 25, and 41 have been corrected (§1 of the 02252008 office action).

**Rejections Under 35 U.S.C. §112, second paragraph**

The Examiner has rejected claims 8, 11, 12, 15, 17, 19, 26, 29, 32-34, 38 and 40-42 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner maintains that claim 8 is indefinite since it is unclear what “including ... profile” (lines 3-4) refers to or modifies. Claim 8 is now amended and the phrase “or other substances” has been deleted from the claim.

The Examiner also states that there is no antecedent basis in claim 7 for “said flavoring agent” (claim 11). Claim 11 has amended to recite “flavoring agents.”

The Examiner states that claim 11 is indefinite since there is no antecedent basis for “said water soluble flavoring agents” (claim 12). Claim 12 has been amended to now recite “ingredients”.

The Examiner states that claim 14 is indefinite since there is no antecedent basis for “said sweetener” (claims 15 & 17). Claims 15 and 17 have been amended to now recite “sweeteners”.

The Examiner states that claim 25 is indefinite since there is no antecedent basis for “lactone monomers” (claim 26, line 2). Claim 26 has been amended to now recite “lactones”.

The Examiner states that claim 1 is indefinite since there is no antecedent basis for “the chewing gum polymers” (claims 32-34). Claims 32-34 are canceled.

The Examiner states that claim 1 is indefinite since there is no antecedent basis for “the at least one biodegradable polymer” (claim 32). Claim 32 is now canceled.

The Examiner states that claim 1 is indefinite since there is no antecedent basis for “the biodegradable polymers” (claims 33-34). Claims 33-34 are now canceled

The Examiner states that claim 25 is indefinite since there is no antecedent basis for “the carbonate monomer” (claim 41, line 2). Claim 41 amended to now recite “cyclic carbonates”.

The Examiner states that claim 1 is indefinite since there is no antecedent basis for “polyester polymers” and “the polymerization of cyclic esters monomers” (claim 42, lines 2-3). Claim 42 has been amended to now recite “polyester copolymers” and “the polymerization of cyclic esters monomers” has been deleted from claim 42.

The Examiner states that claims 19 and 40 do not further limit the claim from which they depend due to the recitation of “0%” in claims 19 and 40. Claims 19 and 40 have been amended to now recite “less than” about 1% and the recitation of “0%” in these claims has been deleted.

The Examiner states that claim 38 is indefinite since it depends upon claim 1, which requires gum ingredients, but claim 38 does not include any gum base ingredients, *and*, even in included, claim 38 would be a duplicate of claim 1 and should be canceled. Claim 38 is directed towards a gum base comprising the polymer of claim 1. Claim 1 is directed to a chewing gum. Claim 38 is not a duplicate of

claim 1. Claim 38 has been amended to include the description of the polymer, as recited in claim 1.

Accordingly, the rejections under 35 U.S.C. §112, second paragraph, have been overcome and should be withdrawn.

**Rejections Under 35 U.S.C. §102(b)**

(¶6) The Examiner has rejected claims 1-8, 11-20, 22, 24-26 and 28-42 under 35 U.S.C. §102(b) as being anticipated by Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, and 42) maintaining that Goldberg et al. discloses a chewing gum free of non-biodegradable polymers, including two different biodegradable polyester copolymers as claimed by the Applicants. The Applicants respectfully traverse this rejection.

As an initial matter, in order for a §102 rejection to be valid, the art cited must teach all limitations required by the claims that define the present invention.

As currently amended, claim 1 requires a chewing gum comprising at least one biodegradable polymer, wherein the molecular weight of said biodegradable polymer is at least 105000 g/mol (Mn), and wherein the chewing gum is substantially free of non-biodegradable polymers.

A closer reading of Goldberg et al. disclose a combination of biodegradable and non-biodegradable polymers. Specifically, Goldberg discloses that

Apart from the degradable copolymers of the present invention, the composition of the gum base is not critical to the present invention. The composition of the gum bases of the present invention can vary .... [and] include both natural and synthetic elastomers and rubbers ... and synthetic elastomers such as butadiene-styrene copolymers, polyisobutylene, isobutylene-isoprene copolymers, polyethylene, mixtures thereof, and the like. (WO 01/47368, page 4, "Detailed Description of the Invention")

In contrast to Goldberg et al., the chewing gum of the present invention is “substantially free” of non-biodegradable polymers and also requires that the molecular weight of the biodegradable polymer is at least 105000 g/mol (Mn) (claim 1).

Since Goldberg et al. do not teach or suggest every element of the present invention as claimed, the Examiner’s rejection under 35 U.S.C. §102(b) should be withdrawn.

**Rejections Under 35 U.S.C. §103(a)**

The Examiner has rejected claims 9 and 10 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. (¶7) In making this rejection, the Examiner maintains that finding the optimum amount of flavoring agent would require nothing more than routine experimentation by one skilled in the art. The Applicants respectfully traverse this rejection.

Goldberg et al. teaches generally the state-of-the-art assumption that biodegradable polymers must be supplemented with non-biodegradable polymers in order to achieve as successful chewing gum. Goldberg et al. primarily focuses on the amounts and types of (biodegradable and non-biodegradable) monomers which may be used in practicing the technology. Goldberg et al. does not teach or suggest the acceptable amounts of flavors (flavorants) which can be used in the chewing gum. In fact, Goldberg et al. only mentions the use of flavorants and does not give any range or amounts to one should use except for a single example with a defined precise amount of a flavor oil (see Example 49 in Goldberg et al.). There are no teachings or suggestions in Goldberg et al. which suggests an optimum amount of flavorant, especially in view of the fact that the single example shows the use of a flavorant at

1.800% (by weight). In addition, one skilled in the art would not look to Goldberg et al. for limits on flavor concentration ranges since Goldberg et al. uses a mixture of biodegradable & non-biodegradable polymers. This type of chewing gum has a different moisture content and hence very different properties from the chewing gum of the present invention, which is substantially free of non-biodegradable polymers. Accordingly, there is no teaching suggestion or motivation in Goldberg et al. that would lead one skilled in the art to utilize the concentration ranges of flavorants claimed in the present invention.

Additionally, the Examiner has rejected claim 23 as being unpatentable over Goldberg et al. in view of Grijpma et al. (US 5,672,367, col. 3, line 4) or Li et al. (6,153,231, col. 7, lines 60-61). (¶8) In making this rejection, the Examiner maintains that it would have been obvious to include a medicinal or pharmaceutical ingredient as an active ingredient in the chewing gum of Goldberg et al. since such an ingredient is a conventional chewing gum component. The Applicants respectfully traverse this rejection.

The addition of active ingredients to a gum can dramatically alter the textural properties of that gum, as these ingredients may be, for instance, acidic, basic, a salt, hydrophobic, hydrophilic, or hydrated. Hence, unless the gum bases are identical, there is no way to predict whether or not a chewing gum with added active ingredients will have the desired textural properties for the consumer. Thus, one skilled in the art would understand that there is no teaching, suggestion or motivation in Goldberg et al. for the addition of other substances (besides flavorants) to the chewing gum. Goldberg et al. is directed to and discloses a chewing gum comprising both biodegradable and non-biodegradable polymers, the use of flavorants for such a gum,

and how one skilled in the art may vary the monomers which comprise the chewing gum to achieve the desired textural properties of the gum.

One skilled in the art reading Goldberg et al., in view of Grijpma et al. would not consider the use of actives in a chewing gum and specifically, the use of actives in a chewing gum that is substantially free from non-biodegradable polymers and where the chewing gum is required to have at least one biodegradable polymer that is at least 150,000 g/mol (Mn), as in claim 1 and dependent claim 23 of the pending application. Thus, there is no teaching suggestion or motivation in Goldberg et al. in view of Grijpma et al. that would lead one skilled in the art to include active ingredients in the present invention.

#### **Double Patenting Rejection**


Claims 1-20, 22-26 and 28-42 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims: 1-62 of co-pending application 10/472,122; claims 1-54 of co-pending application 10/472,154; claims 1-67 of co-pending application 10/528,926; claims 1-67 of co-pending application 10/528,196; claims 1-64 of co-pending application 10/528,930; claims 1-57 of co-pending application 10/528,927; claims 1-55 of co-pending application 10/529,137; and claims 1, 2, 10, 11, 13-18, 24-26 and 28-54 of co-pending application 11/088,109.

Upon indication of allowable subject matter in this case, Applicants will file the appropriate terminal disclaimers in order to overcome these rejections.

The present application as amended herein, is now in form for allowance and early reconsideration and allowance of the claims, as currently pending, is earnestly solicited.

Respectfully submitted,

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